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| 09/712,638 | 11/14/2000 | Isidore Rigoutsos | YOR920000435US1 | 8850 |

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12/04/2003

Robert J Mauri
Ryan Mason & Lewis LLP
Suite 205
1300 Post Road
Fairfield, CT 06430

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| EXAMINER |
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LY, CHEYNE D

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| ART UNIT | PAPER NUMBER |
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1631

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 09/712,638 | Applicant(s) RIGOUTSOS ET AL. | |
| | Examiner Cheyne D Ly | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on September 08, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 13-22, 24 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 23 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicants' arguments filed September 08, 2003 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. Claims 1-12, 23 and 25 are examined on the merits.

LACK OF ENABLEMENT UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for EF1G/PS50040, G protein-coupled receptors, the helix-turn-helix DNA, and C. elegans genome which have properties and features instantly disclosed, does not reasonably provide enablement for any sequence wherein there is not any knowledge about properties or features of the sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

5. This rejection is maintained with respect to claim 4, as recited in the previous office action mailed March 26, 2003.

RESPONSE TO APPLICANT'S ARGUMENT

6. Applicant argues that the method of claim 4 is supported by the specification for one of skill in the art to practice said method with a plurality sequences without any prior knowledge of the properties or features of said sequences. Applicant's argument has been fully considered and found to be unpersuasive due to the fact that a nucleic acid molecule wherein the sequence is known is prior knowledge of the property or feature of said nucleic acid molecule. Therefore, the specification does not enable one of skill in the art to practice said without prior knowledge of properties or features of the sequences if the starting material is a nucleic acid sequence.

7. It is re-iterated that factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

8. It is acknowledged that Applicants provide enablement for EF1G/PS50040, G protein-coupled receptors, the helix-turn-helix DNA, and *C. elegans* genome which have properties

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and features instantly disclosed (Pages 25-48). However, Applicants do not reasonably provide enablement for the use the method in this instant application with any sequence wherein there is not any knowledge about the properties or features of the sequence.

Consistent with the scope of claim 4, a sequence in itself is a specific property or feature of the said sequence. The specification lacks sufficient direction for one skilled in the art use the method in this instant application with any sequence wherein there is not any knowledge about the properties or features of the sequence. Therefore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the method of this instant application for a sequence to which there is no knowledge about properties or features of the said sequence without undue experimentation.

LACK OF WRITTEN DESCRIPTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Consistent with the scope of claim 4, a sequence in itself is a specific property or feature of the said sequence. Therefore, the specification lacks sufficient description of a sequence wherein there is not any knowledge of the properties or features of the said sequence.

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11. This rejection is maintained with respect to claim 4, as recited in the previous office action mailed March 26, 2003.

RESPONSE TO APPLICANT'S ARGUMENT

12. Applicant argues that the method of claim 4 is adequately supported by the instant specification. The said argument has been found to be unpersuasive due to the fact a sequence in itself is prior knowledge a property or feature of said sequence. It has not been found the instant specification wherein Applicant discloses the starting material of the claimed invention wherein the sequence is an entity is not known.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15. This rejection is maintained with respect to claim 1-12, as recited in the previous office action mailed March 26, 2003.

16. Specific to claims 1, line 4; 2, lines 3 and 5; 5, line 2; and 25, line 7, the phrase "candidate sequence" or term "patterns" cause the claim to be vague and indefinite. It is unclear what criteria are being used to determine that a sequence is a candidate sequence. Is it sequence identity, similarity or distribution? Clarification of the metes and bounds is required. Claims 3, 4 and 6-12 are rejected due to being directly or indirectly dependent from claim 1.

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RESPONSE TO APPLICANT'S ARGUMENT

17. Applicant argues by pointed to support (page 6, lines 13-15) that "the candidate sequence is a sequence that may or may not be included as a member of the family of sequences."

Applicant's argument and pointed to support have been fully considered and found to be unpersuasive due to the pointed to support does not help Applicant resolve the vague and indefinite issue of the instant claim.

CLAIM REJECTIONS UNDER - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 1-8, 10-12, 23 and 25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Benson et al. (1997).

RESPONSE TO APPLICANT'S ARGUMENT

20. Applicant argues that Benson et al. does not disclose a method for either discovering a plurality of patterns common to a plurality of sequences in a set of sequences, and/or determining if a candidate sequence comprises a predetermined number of the patterns as in independent claims 1, 23, and 25. Applicant's argument has been fully considered and found to be unpersuasive as discussed below.

21. Benson et al. discloses the NCBI has created the UniGene collection of unique human genes (page 2, EST data §, lines 16-18). UniGene starts with human entries in the PRI

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division of GenBank, combines these with human ESTs and creates clusters of sequences that share virtually identical 3' untranslated regions (page 2, EST Data §, lines 14-23).

22. It is re-iterated that Benson et al. discloses GenBank contained 602, 072, 354 nucleotide bases from 920,588 different sequences (Page 1, column 2, lines 7 and 8), as in claims 4 and

6. "Unigene starts with human entries in the primate (PRI) division of GenBank, combines these with human ESTs and creates clusters of sequences that share virtually identical 3' untranslated regions (3'UTRs) (Page 2, column 2, lines 53-57), as in claims 2 and 7. "One of the most frequent uses of GenBank is sequence similarity searching" (Page 5, column 1, lines 41 and 42", the above disclosures anticipate the limitations of claim 1. "NCBI offers the BLAST family of search programs to perform fast searching with rigorous statistical methods for judging the significance of matches" (Page 5, column 1, lines 42-44), as in claim 3.

NCBI builds GenBank primarily from the direction submission of sequence data from authors and secondarily from scanning the journal literature (Page 1, column 1, lines 13-15), as in claim 5. "WWW access to BLAST currently offers two interfaces, a 'Basic' version with default search parameters and an 'Advanced' option which allows customization of the parameters. A new graphical version called PowerBLAST, designed for rapid analysis and annotation of large contigs of genomic sequence data" (Page 5, column 1, lines 44-49).

"Since the three-dimensional structure information has been linked to the set of protein sequences, users can easily determine as set of sequence neighbors for a given sequence and then locate and visualize structures for members of the neighbor set (Page 5, column 1, lines 34-40), the above disclosures anticipate the limitations of claims 8 and 10-12. "The server/client version of Entrez operates with a client program on a user's machine over the

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Internet connected to a server located at NCBI. Client programs for Macintosh, PC and UNIX computers can be obtained by downloading from 'ncbi.nlm.nih.gov' (Page 5, column 1, lines 26-30), the above disclosures anticipate the limitations of claims 23 and 25.

CONCLUSION

23. NO CLAIM IS ALLOWED.

24. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

25. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

26.

27. This application contains claims 13-22, 24, and 26 drawn to an invention nonelected without traverse in the previous Office Action mailed March 26, 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

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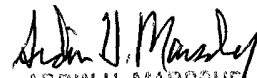
28. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 872-9306.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

31. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
11/28/03


ARMIN H. MARSCHEL
PRIMARY EXAMINER